REMARKS/ARGUMENTS

Claims 1-21, 25-31, 35, 37, 38 and 40-47 are pending. Claims 1-16 were withdrawn. Claims 17, 25 and 35 have been amended. Support for the amendment can be found at least at paragraphs [00037] to [00045]. Thus no new matter has been added with the amendment. Reconsideration of this Application and entry of this Amendment is respectfully requested.

35 U.S.C. §103 Rejections

Obviousness is a question of law, based on the factual inquiries of 1) determining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966). To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). See MPEP 2143.03. The Applicant respectfully asserts that the cited references fail to teach or suggest all the claim limitations.

A. Claims 17-25, 28-38, 40, 41, 43-45 and 47 have been rejected under 35 U.S.C.§ 103(a) as being unpatentable over Fearnot (US Patent 5,380,299) in view of Mao et al., (US Patent Publication 2003/0022216).

The Applicants submit that the Fearnot patent in view of the Mao publication, fails to disclose, teach, or suggest all of the claim limitations of independent claims 17, 25 and 35. Specifically, Fearnot in view of Mao does not disclose teach or suggest:

1) a drug-polymer coated stent that includes a stent framework, a laminated drug-polymer coating disposed on the stent framework, the laminated drug-polymer coating including a plurality of thin drug-polymer layers, wherein the thin drug-polymer layers include a first therapeutic agent and a cured first polymer, and at least one thin barrier layer positioned between a first thin drug-polymer layer and a second thin drug-polymer layer, wherein the at least one thin barrier layer includes a cured second polymer, wherein the cured second polymer excludes drug interaction between the first thin drug-polymer layer and the second thin drug-polymer layer adjacent the at least one barrier layer, as recited in independent claim 17;

2) a system for treating a vascular condition, that includes a catheter and a coated stent coupled to the catheter, the coated stent including a stent framework and a

laminated drug-polymer coating disposed on the stent framework, the laminated drug-polymer coating including a plurality of thin drug-polymer layers and at least one thin barrier layer positioned between a first thin drug-polymer layer and a second thin drug-polymer layer, wherein the thin drug-polymer layers include a first therapeutic agent and a cured first polymer and wherein the at least one thin barrier layer includes a cured second polymer, wherein the cured second polymer excludes drug interaction between the first thin drug-polymer layer and the second thin drug-polymer layer adjacent the at least one barrier layer, as recited in independent claim 25; and

3) a method of treating a vascular condition that includes the step of inserting a drug-polymer coated stent within a vessel of a body, the drug-polymer coated stent including a laminated drug-polymer coating having a plurality of thin drug-polymer layers and at least one thin barrier layer positioned between a first thin drug-polymer layer and a second thin drug-polymer layer, wherein the thin drug-polymer layers include a first therapeutic agent and a cured first polymer and wherein the at least one thin barrier layer includes a cured second polymer, wherein the cured second polymer excludes drug interaction between the first thin drug-polymer layer and the second thin drug-polymer layer adjacent the at least one barrier layer as recited in independent claim 35.

Most specifically, Fearnot does not teach at least one thin barrier layer positioned between a first thin drug-polymer layer and a second thin drug-polymer layer, wherein the thin drug-polymer layers include a first therapeutic agent and a cured first polymer and wherein the at least one thin barrier layer includes a cured second polymer, wherein the cured second polymer excludes drug interaction between the first thin drug-polymer layer and the second thin drug-polymer layer adjacent the at least one barrier layer as recited in claims 17, 25 and 35.

At most, Fearnot teaches a method of coating a medical device surface by dipping the device into a solution containing a thrombolytic agent, allowing the solution to dry and repeating the dipping and drying, if necessary, to obtain the desired concentration or quantity of the thrombolytic agent on the device surface. Figure 5 of the Fearnot patent teaches a stent framework having a multi-layer coating, the multi-layer coating having three layers of an antithrombogenic agent and three layers of a thrombolytic agent applied over the antithrombogenic layers (see Fearnot col. 3 lines 47-50). Nowhere within the cited portions or

the entirety of the Fearnot patent, does the Fearnot patent teach or fairly suggest that any of the layers of the multi-layer coating is a barrier layer having a cured second polymer, wherein the cured second polymer excludes drug interaction between adjacent thin drug-polymer layers as claimed and described by the Applicants.

The Examiner contends that "It is inherent that the layers will block the drug interactions between outer and inner layers for at least a small amount of time" (see, Response to Arguments, page 6 of the current Office Action). The Applicant traverses this allegation that the layers inherently block the drug interactions between outer and inner layers for at least a small amount of time. Further, the Examiner has offered no proof that this occurs, simply making a conclusory statement of inherency. Regardless, the Applicants claims are addressed to excluding drug interaction between the first thin drug-polymer layer and the second thin drug-polymer layer adjacent the at least one barrier layer, not between inner and outer layers as alleged by the Examiner. Thus, the mere fact that the Fearnot patent teaches a multi-layer coating does not necessarily teach that any of the layers are barrier layers. Therefore, the Fearnot patent does not teach at least one thin barrier layer positioned between one or more thin drug-polymer layers, as recited in claims 17, 25 and 35.

The Mao publication does not cure these defects. The Examiner cites to Mao for teaching methods for providing surface coatings on objects such as stents by coating and curing the coatings through cross-linking and thermal activation for the purpose of providing a stable banded coating and alleges that it would have been obvious to one having ordinary skill in the art at the time the invention was made to cure the coatings of Fearnot with the methods provided by Mao in order to cure and bond the coatings to each other and the support member (see, page 3 of the current office action). The Applicant traverses this allegation of obviousness.

Mao teaches a method of preparing a substrate surface to reduce or eliminate non specific binding and enable specific binding. Mao does not teach any method of curing a coating that has been added to a drug coated stent. The Applicant claims are directed to a thin barrier layer having a cured polymer positioned between a first drug layer and a second drug layer. Mao only teaches preparing the substrate surface not a coating on a substrate surface. Thus, one of ordinary skill in the art at the time of the invention would not cure the coatings of Fearnot with the methods of Mao. For at least this reason, claims 17, 25 and 35 are patentable over the Fearnot patent in view of the Mao publication.

Claims 18-21, 28-31, 37, 40, 41, 43-45 and 47 each depend from one of independent claims 17, 25 and 35 and include all of the limitations of their respective independent claim. For at least this reason, dependent claims 18-21, 28-31, 37, 40, 41, 43-45 and 47 are patentable over the Fearnot patent in view of the Mao publication. Claims 22-24, 34, 36 and 38 were cancelled in the amendment to the claims filed June 12, 2006. The Applicants respectfully request the withdrawal of the rejection of claims 17-25, 28-38, 40, 41, 43-45 and 47 as being unpatentable over the Fearnot patent in view of the Mao publication.

B. Claims 26 and 27 have been rejected under 35 U.S.C.§ 103(a) as being unpatentable over Fearnot in view of Mao and in further view of Guruwaiya (US Patent 6,251,136).

Claims 26 and 27 depend from independent claim 25 and include all of the elements and limitations of independent claim 25 and, thus, are allowable for at least the same reasons as those stated above for claim 25. Furthermore, where an independent claim is non-obvious, any claim depending therefrom is also non-obvious. *See*, MPEP 2143. Applicants, therefore, request the withdrawal of the rejection of dependent claims 26 and 27 under § 103(a) as being unpatentable over Fearnot in view of Mao and in further view of Guruwaiya.

C. Claims 42 and 46 have been rejected under 35 U.S.C.§ 103(a) as being unpatentable over Fearnot in view of Mao and in further view of Helmus et al., (US Patent 5,447,724).

Claims 42 and 46 depend from independent claims 17 and 25, respectively, and include all of the elements and limitations of independent claims 17 or 25 and, thus, are allowable for at least the same reasons as those stated above for claims 17 and 25. Furthermore, where an independent claim is non-obvious, any claim depending therefrom is also non-obvious. *See*, MPEP 2143. Applicants, therefore, request the withdrawal of the rejection of dependent claims 42 and 46 under § 103(a) as being unpatentable over Fearnot in view of Mao and in further view of Helmus.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5021.

Respectfully submitted,

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